UNITED STATES DISTRICT COURT
THE SOUTHERN DISTRICT OF OHIO
EASTERN DIVISION

IN RE: DAVOL, INC./C.R. BARD, INC., POLYPROPYLENE HERNIA MESH PRODUCTS LIABILITY LITIGATION	**Case No. 2:18-md-2846** **CHIEF JUDGE EDMUND A. SARGUS** **Magistrate Judge Kimberly A. Jolson**
This Document Relates to: ANTONIO MILANESI AND ALICIA MORZ DE MILANESI	**Civil Action No. _____**

COMPLAINT

Plaintiffs, Antonio Milanesi and Alicia Morz De Milanesi, ("Plaintiffs") file this Complaint pursuant to Case Management Order 2 (Providing for Direct Filing of Cases in MDL No. 2846) and are to be bound by the rights, protections and privileges and obligation of that Order. This Complaint for damages against Defendants, C.R. Bard, Inc., and Davol, Inc. ("Defendants") and in support thereof, states the following:

1. This is a medical device civil tort action brought on behalf of the Plaintiffs arising out of the failure of the Defendants' hernia mesh products, the Ventralex Hernia Patch mesh (hereinafter also referred to as "Ventralex" or "product"). As a result of being implanted with the Defendants' hernia mesh product, Plaintiff suffered permanent injuries and significant pain and suffering, emotional distress, monetary losses, and diminished quality of life. The Plaintiffs respectfully seek damages in excess of $75,000.00 for all damages to which they may be legally entitled.

STATEMENT OF PARTIES

2. Plaintiffs are citizens and residents of the County of Escambia, State of Florida, and the United States.

3. Defendant Davol, Inc. ("Davol") is a corporation that is incorporated under the laws of the State of Rhode Island. Davol has its principal place of business in the State of Rhode Island. It manufactures the Ventralex and is located at 100 Crossings Boulevard, Warwick, Rhode Island. Davol is a medical device company involved in the research, development, testing, manufacture, production, marketing, promotion and/or sale of medical devices including the Ventralex.

4. Defendant C. R. Bard, Inc. ("Bard") is a corporation that is incorporated under the laws of the State of New Jersey. Bard's principal place of business is located at 730 Ventral Avenue, Murray Hill, New Jersey, 07974. Bard is a multinational marketer, promoter, seller, producer, manufacturer, and developer of medical devices. Bard controls the largest market share of the hernia mesh market. It is the corporate parent/stockholder of Davol and participates in the manufacture and distribution of the Ventralex. Bard also manufactures and supplies Davol with material that forms part of the Ventralex. Bard at all times relevant did substantial and continuous business in the State of Florida.

5. At all material times, Bard was responsible for Davol's actions, and exercised control over its functions, specific to the oversight and compliance with applicable safety standards relating to the Ventralex sold in the United States. In such capacity, Bard committed, or allowed to be committed, tortious and wrongful acts, including the violation of numerous safety standards relating to device manufacturing, quality assurance/control, and conformance

with design and manufacturing specifications. Bard's misfeasance and malfeasance caused Plaintiffs to suffer injury and damages.

6. Defendants have purposefully engaged in the State of Florida in the business of developing, manufacturing, publishing information, marketing, distributing, promoting and/or selling, either directly or indirectly, through third parties or other related entities, medical devices including the Ventralex, for which they derived significant and regular income. Defendants intended and reasonably expected that that their defective mesh products, including the Ventralex, would be sold and implanted in the State of Florida and could cause injury in State of Florida.

7. Defendants are individually, jointly and severally liable to Plaintiffs for damages suffered by Plaintiffs arising from the Defendants' design, manufacture, marketing, labeling, distribution, sale and placement of its defective Ventralex at issue in the instant suit, effectuated directly and indirectly through their respective agents, servants, employees and/or owners, all acting within the course and scope of their representative agencies, services, employments and/or ownership.

8. Defendants are vicariously liable for the acts and/or omissions of their employees and/or agents who were at all times relevant hereto acting on behalf of Defendants and within the scope of their employment or agency with Defendants.

VENUE AND JURISDICTION

9. This Court has subject-matter jurisdiction over this action pursuant to 28 U.S.C. §1332(a) based on complete diversity of citizenship between Plaintiffs and all Defendants. The amount in controversy exceeds $75,000.00.

10. Pursuant to Case Management Order 2, Section B (providing for Direct Filing of Cases in MDL No. 2846), Plaintiffs hereby designate the venue of the presumptive place of remand of this claim to be the United States District Court, Northern District of Florida, Pensacola Division. Therefore, Plaintiffs respectfully request that at the time of transfer of this action back to the trial court for further proceedings this case be transferred to the Northern District of Florida, Pensacola Division, as set forth in Case Management Order 2.

11. This Court has personal jurisdiction over Defendants consistent with the United States Constitution and MDL No. 2846 as Plaintiffs' claims arise out of Defendants' transaction of business and the commission of tortious acts within the State of Florida, and by virtue of Defendants' substantial, continuous and systematic contacts with the State of Florida unrelated to Plaintiffs' claims.

FACTS COMMON TO ALL COUNTS

12. The Ventralex Hernia Patch was designed and is manufactured and distributed by Bard and its subsidiary, Davol, who owns the patent on the device that was inserted into Plaintiff's body.

13. Defendants designed, manufactured and distributed the Ventralex that was inserted into Plaintiff Antonio Milanesi's body.

14. Defendants, through its agents, servants, and employees, participated in the manufacture and delivery of the Ventralex that was inserted into Plaintiff's body.

15. Defendants submitted a 510(k) Application to the Federal Drug Administration (*hereinafter* "FDA") in May 2002. Following this 510(k) Application, on July 16, 2002, Ventralex was authorized by the FDA as a Class II medical device and found to be "substantially equivalent" to the Bard Composix Kugel Mesh Patch.

16. Ventralex is a multi-layer polypropylene and expanded polytetraflouroethylene patch marketed by Defendants, as a mesh to be used in repairing hernias and to provide extra reinforcement to the hernia defect.

17. Defendants' Ventralex product contains two layers of polypropylene mesh. Despite claims that this material is inert, a substantial body of scientific evidence shows that this mesh material is biologically incompatible with human tissue and promotes an immune response in a large subset of the population receiving these products. This immune response promotes degradation of the polypropylene mesh, as well as the surrounding tissue, and can contribute to the formation of severe adverse reactions to the mesh.

18. Defendants' statements made to the FDA regarding these devices inadequately relied on predicate devices and not clinical testing or other design verification testing. These statements induced Plaintiff's implanting surgeon and Plaintiff into relying upon Defendants' judgment.

19. Ventralex is designed, indicated, and utilized for permanent implantation in the human body, in the intraabdominal space between the subcutaneous tissue and intestines.

20. Upon information and belief, Defendants' numerous suppliers, of various forms of polypropylene, cautioned all users in their United States Material Safety Data Sheet ("MSDS") that the polypropylene was not to be used for medical applications involving permanent implantation in the human body or permanent contact with internal body fluids or tissues .

21. Defendants failed to warn or notify doctors, regulatory agencies, and consumers of the severe and life-threatening risks associated with polypropylene.

22. Ventralex contains the following components: 1) a "memory recoil ring" component, 2) a layer of expanded polytetraflouroethylene, and 3) two layers of polypropylene mesh.

23. Ventralex has two layers of polypropylene mesh on one side, and an expanded polytetraflouroethylene (*hereinafter* "ePTFE") on the other side. The ePTFE is intended to face the intestines in the intra-abdominal space. The layers of polypropylene are stitched to the ePTFE with polytetraflouroethylene (*hereinafter* "PTFE") monofilament. The design also contains a polytetrafluoroethylene (*hereinafter* "PET") "memory recoil ring" at its periphery. The stated purpose of this ring is only to facilitate initial placement of the mesh by the surgeon, yet, by design, it is left implanted along with the mesh components. The presence of the ring can directly lead to deformation and buckling of the patch as a result of mesh and/or mesh/wound shrinkage, tissue ingrowth, other mechanical forces acting on the ring, or of plane positioning and repositioning of the patch (noting that the surface to which it is attached is not actually flat even initially), and initial lack of flatness of the ring plane. Additionally, the above-noted forces on the ring can cause the ring to break, causing an array of problems including, but not limited to, bowel perforation.

24. The polypropylene mesh and ePTFE used in the manufacture the Ventralex, which was implanted into Antonio Milanesi, is not suited for implantation into the human body due to its small pore size and weave, high volume of material utilized, selection of polypropylene resin, and other design features. These design aspects lead to adverse tissue reactions in the body, which directly lead to complications.

25. The Ventralex implanted in Plaintiff Antonio Milanesi's was designed, manufactured, sold and distributed by Defendants to be used by surgeons for hernia repair

surgeries and was further represented by Defendants to be an appropriate, cost-effective and suitable product for such purpose.

26. The polypropylene mesh used in the manufacture of the Ventralex, which was implanted into Plaintiff's body, is unreasonably dangerous, defective, and negligently designed in the following ways:

a) The weave of the mesh produces very small interstices which allow bacteria to enter and hide from the host defenses designed to eliminate them. The bacteria can secrete an encasing slime (biofilm) which further serves to protect them from destruction by white blood cells and macrophages.

b) Polypropylene is impure: there is no such thing as pure polypropylene (PP). PP contains about 15 additional compounds which are leached from the PP and are toxic to tissue which enhances the inflammatory reaction and the intensity of fibrosis.

c) Mesh was shown to be not inert in 2003 with flaking and fissuring demonstrated by scanning electron microscopy which leads to degradation and release of toxic compounds. This enhances the inflammatory and fibrotic reactions.

d) With loss of PP due to degradation, the surface area is greatly increased, thus providing greater areas for bacterial adherence and more elution of toxic compounds from the PP, and also the freed toxic PP itself, all of which increases the inflammatory reaction and intensity of fibrosis.

e) By 1998 polypropylene mesh was known to shrink 30-50%.

f) Heat begins the process of degradation.

g) Predominate infection/inflammation was noted at least in 2007 in explanted samples.

h) Allergic reactions occur with polypropylene after implantation.

i) Polypropylene is subject to oxidation by acids produced during the inflammatory reaction which caused degradation and loss of compliance.

j) Mesh porosity is important for tissue ingrowth, with low porosity decreasing tissue incorporation. Porosity also affects the inflammatory and fibrotic reaction. With mechanical stress the porosity of the pores is decreased.

k) Pore size should be at least 3mm. The Ventralex pore size is much less than this; it has an effective porosity of 1mm.

l) Observation of mesh under the scanning electron microscope reveals that very small interstices exist between the mesh fibrils, which are too small for a macrophage to enter to destroy incubating bacteria. Some bacteria are capable of degrading polypropylene.

m) Polypropylene is known to depolymerize, cross-link, undergo oxidative degradation by free radicals, and stress crack after implantation in the human body.

n) Polypropylene migrates to lymph nodes when there is a foreign body giant cell reaction.

o) The large surface area promotes wicking of fluids and bacteria and is a "bacterial super highway" which provides a safe haven for bacteria.

p) Common complications associated with PP include restriction of abdominal wall mobility and local wound disturbances. Often failures of PP include persistent and active inflammatory processes, irregular or low formation of scar tissue and unsatisfying integration of the mesh in the regenerative tissue area.

q) Klosterhalfen published a series of 623 explanted mesh samples removed for pain, infection and recurrence. There are also reports of mesh migration and erosion into the sigmoid colon. Reduced mobility of the abdominal wall has also been found. Moreover, the rate of chronic pain after mesh hernia repair ranges from 4-40%. Thus, Defendants should have been aware of these issues with polypropylene.

r) Fibrotic bridging is often observed in mesh variants with pore sizes of 1mm or less, which is the typical pore size of heavyweight, small pore PP mesh, like the Ventralex.

s) The ePTFE patch shrinkage rates are the largest as a microporous mesh. Due to the microporous design, the ePTFE is embedded entirely in a fibrous capsule, wherein its collagen fibers are arranged parallel to the surface of the ePTFE patches. During wound healing, collagen fibers parallel to the ePTFE surface cause a maximum wound contraction with a reduction of the patch size up to 50%.

27. A malfunction of this device can lead to bowel perforations and/or chronic intestinal fistulae (abdominal connections or passageways between the intestines and other organs), as well as other chronic and debilitating conditions.

28. The Ventralex implanted into Plaintiff Antonio Milanesi was manufactured in the same or in a similar manner as recalled Composix Kugel patches. Plaintiff Antonio Milanesi's Ventralex contained the same or similar "memory recoil ring," the same or similar polypropylene mesh, and the same or similar ePTFE layer. Plaintiff Antonio Milanesi suffered symptoms and injuries consistent with the symptoms and injuries described by the recall information as suffered by the other individuals affected by the defective Composix Kugel Patches.

29. Upon information and belief Defendants failed to comply with the FDA application and reporting requirements.

30. Upon information and belief Defendants were aware of the high degree of complication and failure rate associated with the Ventralex.

31. Upon information and belief Defendants were aware of the defects in the manufacture and design of the Ventralex.

32. Upon information and belief, Defendants were and are aware of the defects in the manufacture and design of the Ventralex and chose, and continue to choose, not to issue a recall of these products, including the Ventralex implanted in the Plaintiff Antonio Milanesi, in the face of a high degree of complication and failure rates.

33. Upon information and belief, Defendants manipulated, altered, skewed, slanted, misrepresented, and/or falsified pre-clinical and/or clinical studies to bolster the perceived performance of the Ventralex.

34. Upon information and belief, Defendants paid doctors, surgeons, physicians, and/or clinicians to promote the Ventralex, but did not readily disclose this information.

35. Defendants failed to properly investigate and disclose adverse event reports to the FDA and other regulatory agencies worldwide.

36. Defendants failed to implement adequate procedures and systems to report, track, and evaluate complaints and adverse events.

37. Defendants marketed the Ventralex to the medical community and to patients as safe, effective, reliable, medical devices for the treatment of hernia repair, and as safer and more effective as compared to the traditional products and procedures for treatment, and other competing mesh products. Defendants' did not undergo pre-market approval for the Ventralex and are, therefore, prohibited by the FDA from asserting superiority claims.

38. Despite diligent investigation by Plaintiff Antonio Milanesi into the cause of his injuries, including consultations with his medical providers, the nature of his injuries and damages, and their relationship to the Ventralex was not discovered, and through reasonable care and diligence could not have been discovered until a date within the applicable statute of limitations for filing Plaintiffs' claims. Therefore, under appropriate application of the discovery rule, Plaintiffs' suit was filed well within the applicable statutory limitations period.

39. Plaintiff did not learn of Defendants' wrongful conduct until a date within the applicable statute of limitations. Further, Plaintiffs could not have reasonably discovered the Defendants' wrongful conduct, including, but not limited to, the defective design and/or manufacturing of the product until a date within the statute of limitations. Therefore, under appropriate application of the discovery rule, Plaintiffs' suit was filed well within the statutory limitations period.

40. Defendants were negligent to Plaintiff Antonio Milanesi in the following respects:

41. Defendants failed to perform or rely on proper and adequate testing and research in order to determine and evaluate the risks and benefits of the Ventralex.

42. Defendants failed to design and establish a safe, effective procedure for removal of the Ventralex; therefore, in the event of a failure, injury, or complications it is difficult to safely remove the Ventralex.

43. Defendants provided incomplete, insufficient, and misleading information to physicians in order to increase the number of physicians using the Ventralex for the purpose of increasing their sales. By so doing, Defendants caused the dissemination of inadequate and misleading information to patients, including the Plaintiff Antonio Milanesi.

44. The Ventralex was utilized and implanted in a manner foreseeable to Defendants.

45. The Ventralex implanted into Plaintiff Antonio Milanesi was in the same or substantially similar condition as when it left the possession of the Defendants, and in the condition directed by the Defendants.

46. On or about July 11, 2007, Plaintiff underwent surgery for repair of an umbilical hernia by Dr. Karanbir Gill at Sacred Heart Hospital in Pensacola, Florida. A Ventralex Hernia Patch mesh**,** Reference number 0010303 and Lot number DARB0016, was implanted to repair the hernia defect.

47. At the time of his operation, Plaintiff Antonio Milanesi was not informed of, and had no knowledge of the complaints, known complications and risks associated with the Ventralex.

48. Plaintiff Antonio Milanesi was never informed by Defendants of the defective and dangerous nature of the Ventralex.

49. At the time of his implant, neither Plaintiff Antonio Milanesi nor his physicians were aware of the defective and dangerous condition of the Ventralex.

50. On or about May 26, 2017, Plaintiff underwent an additional surgery by Dr. Michael Caluda at Sacred Heart Hospital remove the infected Ventralex and small bowel fistula. The surgeon noted that a loop of small bowel was densely adherent to the mesh and an erosion of the small bowel was evident into an abscess cavity involving a portion of the mesh. This caused the surgeon to perform a small bowel resection, anastomosis, removal of the infected hernia mesh, abscess cavity and small bowel fistula and repair of the ventral hernia. Plaintiff Antonio Milanesi was injured severely and permanently.

51. On or about June 1, 2017, Plaintiff underwent an additional surgery by Dr. Michael Caluda at Sacred Heart Hospital in Pensacola, Florida to repair a high-grade small bowel obstruction. The surgeon performed enterolysis and freed the small bowel obstruction. Plaintiff Antonio Milanesi was injured severely and permanently.

52. Plaintiff Antonio Milanesi has suffered and will continue to suffer physical pain as well as mental anguish and emotional distress.

53. Plaintiff Antonio Milanesi has also incurred substantial medical bills and has suffered loss of other monies due to the defective hernia patch that was implanted in his body.

54. Plaintiff also requires further medical treatment, including likely need for future surgeries.

ESTOPPEL AND TOLLING OF STATUTE OF LIMITATIONS

55. Due to Defendant's acts of fraudulent concealment, they are estopped from relying on any statutes of limitations or repose. Such acts include Defendant's intentional concealment from Plaintiffs and the general public that the Ventralex is defective, while continuing to market the product with the adverse effects described in this Complaint.

56. Given Defendant's affirmative actions of concealment by failing to disclose information about the defects known to them but not the public—information over which Defendants had exclusive control—and because Plaintiff Antonio Milanesi could not reasonably have known the Ventralex was defective, Defendants are estopped from relying on any statutes of limitations that might otherwise be applicable to the claims asserted in this Complaint.

COUNT I
Negligence

57. Plaintiffs incorporate by reference the allegations in all prior paragraphs.

58. Defendants were negligent to Plaintiffs in the following respects:

59. Defendants at all times mentioned had a duty to properly manufacture, test, inspect, package, label, distribute, market, examine, maintain, supply, provide proper warnings and prepare for use the Ventralex Hernia Patch.

60. Defendants at all times mentioned knew or in the exercise of reasonable care should have known, that the Ventralex Hernia Patches were of such a nature that they were not properly manufactured, tested, inspected, packaged, labeled, distributed, marketed, examined, sold, supplied, prepared and/or provided with the proper warnings, and were unreasonably likely to injure Ventralex Hernia Patch users.

61. Defendants so negligently and carelessly designed, manufactured, tested, failed to test, inspected, failed to inspect, packaged, labeled, distributed, recommended, displayed, sold, examined, failed to examine and supplied the Ventralex Hernia Patch, that they were unreasonably dangerous and unsafe for the use and purpose for which it was intended.

62. Defendants were aware of the probable consequences of the Ventralex Hernia Patch. Defendants knew or should have known the Ventralex Hernia Patch would cause serious injury and they failed to disclose the known or knowable risks associated with the Ventralex

Hernia Patch. Furthermore, Defendants willfully and deliberately failed to avoid those consequences, and in doing so, Defendants acted in conscious disregard of the safety of Plaintiff Antonio Milanesi.

63. Defendants owed a duty to Plaintiff Antonio Milanesi to adequately warn his treating physicians of the risks of degradation, infection, contracture, shrinkage, breakage, separation, tearing and splitting associated with the Ventralex Hernia Patch and the resulting harm and risk it would cause patients.

64. Defendants breached their duty by failing to comply with state and federal regulations concerning the study, testing, design, development, manufacture, inspection, production, advertisement, marketing, promotion, distribution, and/or sale of the Ventralex Hernia Patch.

65. As a direct and proximate result of the duties breached, the Ventralex Hernia Patch used in Plaintiff Antonio MiIlanesi's hernia repair surgery failed, resulting in much pain and suffering, mental anguish, emotional distress, doctor visits, subsequent procedures, and hefty medical bills

66. As a direct and proximate result of the duties breached, Plaintiff Antonio Milanesi suffered injuries and damages as summarized in this Complaint. Plaintiff has suffered and will continue to suffer physical pain and suffering, as well as mental anguish and emotional distress. Plaintiff has also incurred substantial medical bills and loss of other monies due to the defective Ventralex Hernia Patch that was implanted.

67. Defendants' conduct in continuing to market, sell and distribute the Ventralex Hernia Patch after obtaining knowledge that the products were failing and not performing as represented and intended, showed complete indifference to or a conscious disregard for the

safety of others, justifying an award of additional damages for aggravating circumstances in such a sum which will serve to deter Defendants and others from similar conduct in the future.

COUNT II
Strict Liability – Manufacturing Defect

68. Plaintiffs incorporate by reference the allegation in all prior paragraphs.

69. Defendants expected and intended the Ventral Hernia Patch to reach users such as Plaintiff Antonio Milanesi in the condition in which the product was sold.

70. The implantation of the Ventral Hernia Patch in Plaintiff's body was medically reasonable and was a type of use that Defendants intended and foresaw when they designed, manufactured and sold the product.

71. When the Ventral Hernia Patch was implanted in Plaintiff's body it was defectively manufactured.

72. Defendants' poor quality control and general non-compliance resulted in the non-conformance of the Ventral Hernia Patch implanted in Plaintiff. The implanted product did not conform to Defendants' intended manufacturing and design specifications.

73. Upon information and belief, Defendants utilized substandard and adulterated polypropylene and raw materials used to make the Ventral Hernia Patch, which deviated from Defendants' material and supply specifications.

74. As a direct and proximate result of the defective manufacture of the Ventral Hernia Patch, Plaintiff suffered injuries and damages as summarized in this Complaint. Plaintiff has suffered and will continue to suffer physical pain and suffering, as well as mental anguish and emotional distress. Plaintiff has also incurred substantial medical bills and has suffered loss of other monies due to the defective Ventralex Hernia Patch that was implanted.

COUNT III

Strict Liability – Design Defect

75. Plaintiffs incorporate by reference the allegations in all prior paragraphs.

76. Defendants are strictly liable to Plaintiff Antonio Milanesi in the following respects:

77. Defendants designed, manufactured, assembled, distributed, conveyed and/or sold the Ventralex Hernia Patch for hernia repair surgery.

78. The Composix Kugel Patches subject to the Class I recall were defective because they failed to perform safely and effectively for the purpose they were originally designed. While the Plaintiff's Ventralex Hernia Patch was not included in the Class I recall, it is included in the same product line, in that it also contains the "memory recoil ring" and polypropylene mesh as in the recalled products.

79. At all times mentioned, the Ventralex Hernia Patch was substantially in the same condition as when it left the possession of Defendants.

80. The Ventralex Hernia Patch implantation into Plaintiff was medically reasonable at the time it was implanted into her by her surgeon and was a type of use that Defendants intended and foresaw when they designed, manufactured and sold the product.

81. The Ventralex Hernia Patches, like the one found in Plaintiff, at the time they left the possession of Defendants were inherently dangerous for their intended use and were unreasonably dangerous products which presented and constituted an unreasonable risk of danger and injury to Plaintiff as follows:

i. The Ventralex Hernia Patch was sold in a defective condition by design and manufacture;
ii. The Ventralex Hernia Patch as designed and manufactured was unsafe to Plaintiff Antonio Milanesi;
iii. The Ventralex Hernia Patch as designed and manufactured was unreasonably dangerous to Plaintiff;

iv. The Ventralex Hernia Patch did not perform safely as an ordinary consumer/patient, like Plaintiff, would expect;
v. The Ventralex Hernia Patch as designed and manufactured was unsafe for its intended use;
vi. Defendants failed to warn the end user about the dangers and risks of the product;
vii. Defendants knew the component parts of the Ventralex Hernia Patch as implemented through design and/or manufacture could cause injury to the end user;
viii. Failing to implement an adequate, safe and effective "memory recoil ring" and/or its interaction with the mesh of the Ventralex Hernia Patch to withstand the foreseeable stresses they would be subject to within the intra-abdominal space;
ix. Failing to avoid migration of the Ventralex Hernia Patch and/or its components from the initial site of the hernia repair surgery.
x. Any other acts or failures to act by Defendants regarding the studying, testing, designing, developing, manufacturing, inspecting, producing, advertising, marketing, promoting, distributing, and/or sale of Ventralex Hernia Patches for hernia repair surgery as will be learned during discovery.

82. As a result of the defective design and/or manufacture of the Ventralex Hernia Patch, there was an unreasonable risk of severe adverse reactions to the mesh or its components including: chronic infections; chronic pain; recurrence of hernia; foreign body response; rejection; infection; scarification; improper wound healing; excessive and chronic inflammation; allergic reaction; adhesions to internal organs; erosion; abscess; fistula formation; granulomatous response; seroma formation; nerve damage; tumor formation, cancer, tissue damage and/or death; and other complications

83. When affixed to the body's tissue, the impermeable Ventralex Hernia Patch prevents fluid escape, which leads to seroma formation, and which in turn can cause infection or abscess formation and other complications.

84. The Ventralex Hernia Patch is cytotoxic, immunogenic, and not biocompatible, which causes or contributes to complications such as delayed wound healing, inflammation, foreign body response, rejection, infection, and other complications

85. The risks of the product significantly outweigh any benefits that Defendants contend could be associated with it. Ventralex Hernia Patch incites an intense inflammatory response, leading to encapsulation, deformation, scarification and contraction, migration, erosion and rejection.

86. The polypropylene mesh was in itself dangerous and defective, particularly when used in the manner intended by Defendants. The polypropylene material used in the Ventralex Hernia Patch was substandard, adulterated and non-medical grade, and was unreasonably subject to oxidative degradation within the body, further exacerbating the adverse reactions caused by the product. The Ventralex Hernia Patch polypropylene mesh is unreasonably susceptible to adhesion, perforation or erosion, fistula formation and bowel strangulation or hernia incarceration, and other injuries.

87. The appropriate treatment for complications associated with the Ventralex Hernia Patch involves additional invasive surgery in an attempt to remove the mesh from the body, thus eliminating any purported benefit that the product was intended to provide to the patient.

88. When the Ventralex Hernia Patch was implanted in Plaintiff, there were safer feasible alternative designs for hernia mesh products available.

89. The Ventralex Hernia Patch provides no benefit to consumers over other mesh types and increased the risks to patients implanted with these devices.

90. The Ventralex Hernia Patch implanted in Plaintiff failed to reasonably perform as intended and had to be surgically removed. Thus, further invasive surgery was necessary to repair the very problem that the product was intended to repair, providing only harm and no benefit to her.

91. As a direct and proximate result of the defective and unreasonably dangerous condition of the product, Plaintiff Antonio Milanesi suffered injuries and damages as summarized in this Complaint. Plaintiff has suffered and will continue to suffer physical pain and suffering, as well as mental anguish and emotional distress. Plaintiff has also incurred substantial medical bills and has suffered loss of other monies due to the defective Ventralex Hernia Patch that was implanted

92. Defendants' conduct in continuing to market, sell and distribute the Ventralex Hernia Patch after obtaining knowledge that the products were failing and not performing as represented and intended, showed complete indifference to or a conscious disregard for the safety of others justifying an award of additional damages for aggravating circumstances in such a sum which will serve to deter Defendants and others from similar conduct in the future.

COUNT IV
Negligent Infliction of Emotional Distress

93. Plaintiffs incorporate by reference the allegations in all prior paragraphs.

94. Defendants carelessly and negligently manufactured, designed, developed, tested, labeled, marketed and sold the Ventral Hernia Patch to Plaintiff.

95. Defendants carelessly and negligently concealed the harmful effects of the product from Plaintiff and/or his physician on multiple occasions and continue to do so to this day.

96. Defendants carelessly and negligently misrepresented the quality, safety and efficacy of the Ventral Hernia Patch to Plaintiff and/or his physician on multiple occasions and continue to do so to this day.

97. Plaintiff was directly impacted by Defendants' carelessness and negligence, in that he has sustained, and will continue to sustain, emotional distress, severe physical injuries,

economic losses, and other damages as a direct result of the decision to purchase the Ventral Hernia Patch.

98. Defendants continued to carelessly and negligently misrepresent the quality, safety, efficacy, dangers and contraindications of the Ventral Hernia Patch to Plaintiff and/or his physician, after he sustained emotional distress, severe physical injuries, and economic loss.

99. Defendants continued to carelessly and negligently misrepresent the quality, safety, efficacy, dangers and contraindications of the product to Plaintiff and/or his physician, knowing that doing so would cause him to suffer additional and continued emotional distress, severe physical injuries, and economic loss.

100. As a proximate result of Defendants' conduct, Plaintiff has been injured, sustained severe and permanent pain, suffering, anxiety, depression, disability, impairment, loss of enjoyment of life, loss of care, comfort, and economic damages.

101. As direct and proximate result of the Defendants' conduct, Plaintiff has suffered and will continue to suffer physical pain and suffering, as well as mental anguish and emotional distress. Plaintiff has also incurred substantial medical bills and has suffered loss of other monies due to the defective Ventralex Hernia Patch that was implanted.

102. Defendants' conduct in continuing to market, sell and distribute the Ventralex Hernia Patch after obtaining knowledge that the products were failing and not performing as represented and intended, showed complete indifference to or a conscious disregard for the safety of others justifying an award of additional damages for aggravating circumstances in such a sum which will serve to deter Defendants and others from similar conduct in the future.

COUNT V
Breach of Implied Warranty

103. Plaintiffs incorporate by reference the allegations in all prior paragraphs.

104. At all material times, Defendants manufactured, distributed, advertised, promoted, and sold their Ventralex Hernia Patch.

105. At all material times, Defendants intended for their product to be implanted for the purposes and in the manner that Plaintiff and/or his implanting physician in fact used it; and Defendants impliedly warranted that the product and its component parts was of merchantable quality, safe and fit for such use, and adequately tested.

106. Defendants were aware that consumers, including Plaintiff and/or his physician, would implant their product as directed by the Instructions for Use. Therefore, Plaintiff was a foreseeable user of Defendants' Ventralex Hernia Patch.

107. Defendants' Ventralex Hernia Patch was expected to reach, and did in fact reach consumers, including Plaintiff and/or his physician, without substantial change in the condition in which it was manufactured and sold by Defendants.

108. Defendants breached various implied warranties with respect to the Ventralex Hernia Patch, including the following:

a. Defendants represented to Plaintiff and/or his physician and healthcare providers through labeling, advertising, marketing materials, detail persons, seminar presentations, publications, notice letters, and regulatory submissions that their product was safe. But at the same time, they fraudulently withheld and concealed information about the substantial risks of serious injury associated with using the product;

b. Defendants represented to Plaintiff and/or his physician and healthcare providers that their product was safe and/or safer than other alternative procedures and devices. But

at the same time, they fraudulently concealed information demonstrating that the product was not safer than alternatives available on the market; and

c. Defendants represented to Plaintiff and/or his physician and healthcare providers that their product was more efficacious than alternative procedures and/or devices. But at the same time, they fraudulently concealed information regarding the true efficacy of the Ventralex Hernia Patch.

109. In reliance upon Defendants' implied warranties, Plaintiff individually, and/or by and through his physician, used the Ventralex Hernia Patch as prescribed, and in the foreseeable manner normally intended, recommended, promoted, and marketed by Defendants.

110. Defendants breached their implied warranties to Plaintiff in that their product was not of merchantable quality, nor was it safe and fit for its intended use or adequately tested.

111. As a direct and proximate result of the Defendants' breaches of the aforementioned implied warranties, Plaintiff Antonio Milanesi suffered injuries and damages as summarized in this Complaint. Plaintiff has suffered and will continue to suffer physical pain and suffering, as well as mental anguish and emotional distress. Plaintiff has also incurred substantial medical bills and has suffered loss of other monies due to the defective Ventralex Hernia Patch that was implanted.

COUNT VI
Failure to Warn

112. Plaintiffs incorporate by reference the allegations in all prior paragraphs.

113. In the course of business, Defendants designed, manufactured and sold the Ventralex Hernia Patch to hospitals for hernia repair surgeries.

114. In performing Plaintiff Antonio Milanesi's hernia repair surgery, the operating physician used and inserted into Plaintiff Antonio Milanesi one of the Ventralex Hernia Patch that Plaintiff Antonio Milanesi's hospital purchased from Defendants.

115. At the time of the design, manufacture and sale of the Ventralex Hernia Patch, and more specifically at the time Plaintiff Antonio Milanesi received the Ventralex Hernia Patch, they were defective and unreasonably dangerous when put to their intended and reasonably anticipated use. Further, the Ventralex Hernia Patches were not accompanied by proper warnings regarding significant adverse consequences associated with the Ventralex Hernia Patch.

116. Defendants failed to provide any warnings, labels or instructions of its dangerous propensities that were known or reasonably scientifically knowable at the time of distribution. The reasonably foreseeable use of the products involved significant dangers not readily obvious to the ordinary user of the Ventralex Hernia Patch devices. Defendants failed to warn of the known or knowable injuries associated with malfunction of the Ventralex Hernia Patch, including but not limited to rupture of the patch and severe peritonitis and infection which would require subsequent surgical procedures and could result in severe injuries.

117. The dangerous and defective conditions in the Ventralex Hernia Patches existed at the time they were delivered by the manufacturer to the distributor. At the time Plaintiff Antonio Milanesi had his hernia repair surgery, the Ventralex Hernia Patch was in the same condition as when manufactured, distributed and sold.

118. Plaintiff Antonio Milanesi did not know at the time of surgery that the Ventralex Hernia Patch placed during Plaintiff Antonio Milanesi's surgery or at any time prior thereto, of the existence of the defects or dangerous propensities in the Ventralex Hernia Patches.

119. As a direct and proximate result of Defendants' failure to warn, Plaintiff Antonio Milanesi suffered injuries and damages as summarized in this Complaint. Plaintiff has suffered and will continue to suffer physical pain and suffering, as well as mental anguish and emotional distress. Plaintiff has also incurred substantial medical bills and has suffered loss of other monies due to the defective Ventralex Hernia Patch that was implanted.

120. As such, Defendants breached their duty to warn about known defects and are liable to Plaintiff Antonio Milanesi for the injuries sustained and the costs incurred as a result of using the Ventralex Hernia Patch.

121. The conduct of Defendants in continuing to market, promote, sell and distribute the Ventralex Hernia Patch after obtaining knowledge that the products were failing and not performing as represented and intended, showed a complete indifference to or conscious disregard for the safety of others justifying an award in such sum which will serve to deter Defendants and others from similar conduct.

COUNT VII
Fraud

122. Plaintiffs incorporate by reference the allegations in all prior paragraphs.

123. In the course of business, Defendants designed, manufactured and sold the Ventralex Hernia Patch for hernia repair surgeries.

124. At the time of the design, manufacture and sale of the Ventralex Hernia Patch, and, more specifically, at the time Plaintiff Antonio Milanesi received the Ventralex Hernia Patch, they were defective and unreasonably dangerous when put to their intended and reasonably anticipated use. Further the Ventralex Hernia Patch was not accompanied by proper warnings regarding significant adverse consequences associated with the Ventralex Hernia Patch.

125. Defendants were aware of the dangerous and defective condition of the products and intentionally withheld this information from Plaintiff Antonio Milanesi, Plaintiff Antonio Milanesi's physicians, the FDA, and the general public even though these significant dangers were not readily obvious to the ordinary user of the products, even after a post surgical complication had arisen.

126. Defendants fraudulently represented to Plaintiff Antonio Milanesi, Plaintiff Antonio Milanesi's physicians, and the general public that the Ventralex Hernia Patch was a safe and effective product even though they were fully aware of the dangerous and defective nature of the Ventralex Hernia Patch which likely could, and would, cause injuries such as those suffered by Plaintiff Antonio Milanesi.

127. Plaintiff Antonio Milanesi and his physicians relied upon the fraudulent misrepresentations and concealments of Defendants and allowed for the defective Ventralex Hernia Patch to be implanted.

128. As a direct and proximate result of Defendants' fraudulent misrepresentations and concealments, Plaintiff Antonio Milanesi suffered injuries and damages as summarized in this Complaint. Plaintiff has suffered and will continue to suffer physical pain and suffering, as well as mental anguish and emotional distress. Plaintiff has also incurred substantial medical bills and has suffered loss of other monies due to the defective Ventralex Hernia Patch that was implanted.

129. The conduct of Defendants in continuing to fraudulently market, promote, sell and distribute the Ventralex Hernia Patch while fraudulently concealing knowledge that the products were failing and not performing as represented and intended, showed a complete

indifference to or conscious disregard for the safety of others justifying an award in such sum which will serve to deter Defendants and others from similar conduct.

COUNT VIII
Negligent Misrepresentation

130. Plaintiff incorporates by reference the allegations in all prior paragraphs.

131. Defendants had a duty to accurately and truthfully represent to the medical and healthcare community, Plaintiff, and the public, that the Ventralex had not been adequately tested and found to be a safe and effective treatment. Defendants breached that duty as their representations were false.

132. Defendants failed to exercise ordinary care in the representations concerning their product while they were involved in its manufacture, sale, testing, quality assurance, quality control, and distribution in interstate commerce, because they negligently misrepresented the Ventralex's high risk of unreasonable and dangerous adverse side effects.

133. Defendants also breached their duty in representing to Plaintiff, her physician, and the medical community that their product had no serious side effects different from older generations of similar products and/or procedures.

134. As a foreseeable, direct, and proximate result of Defendants' negligent misrepresentations, they knew or had reason to know, that the Ventralex had been insufficiently tested, or had not been tested at all; and that it lacked adequate and accurate warnings, and created a high risk, or a higher than acceptable reported and represented risk of adverse side effects. Those side effects include pain, graft rejection, graft migration, organ damage, complex seroma, fistula, sinus tract formation, delayed wound closure, infection, sepsis, and death.

135. As a direct and proximate result of Defendants' conduct, Plaintiff Antonio Milanesi suffered injuries and damages as summarized in this Complaint. Plaintiff has suffered

and will continue to suffer physical pain and suffering, as well as mental anguish and emotional distress. Plaintiff has also incurred substantial medical bills and has suffered loss of other monies due to the defective Ventralex Hernia Patch that was implanted.

COUNT IX
Gross Negligence

136. Plaintiffs incorporate by referenced the allegations in all prior paragraphs.

137. Defendants' wrongs were aggravated by the kind of malice, fraud, and grossly negligent disregard for the rights of others, the public, and Plaintiff, for which the law would allow, and for which Plaintiff will seek at the appropriate time, the imposition of exemplary damages. That is because Defendants' conduct, including the failure to comply with applicable federal standards was specifically intended to cause substantial injury to Plaintiff. Their conduct, when viewed objectively from Defendants' standpoint at the time of the conduct, involved an extreme degree of risk, considering the probability and magnitude of the potential harm to others; and Defendants were actually, subjectively aware of the risk involved but nevertheless proceeded with conscious indifference to the rights, safety, or welfare of others; or included Defendants' false material representations, with their knowledge that it was false or with reckless disregard as to its truth and as a positive assertion, with the intent that Plaintiff would act upon their representation.

138. Plaintiff relied on the representation and suffered injury as a proximate result of this reliance.

139. Plaintiff therefore will seek to assert claims for exemplary damages at the appropriate time, in an amount within the jurisdictional limits of the Court.

140. Plaintiff also alleges that Defendants' acts and omissions, whether taken singularly or in combination with others, constitute gross negligence, proximately causing their

injuries. In that regard, Plaintiff will seek exemplary damages in an amount to punish Defendants for their conduct, and to deter other manufacturers from engaging in such misconduct in the future.

141. As a direct and proximate result of Defendants' conduct, Plaintiff Antonio Milanesi suffered injuries and damages as summarized in this Complaint. Plaintiff has suffered and will continue to suffer physical pain and suffering, as well as mental anguish and emotional distress. Plaintiff has also incurred substantial medical bills and has suffered loss of other monies due to the defective Ventralex Hernia Patch that was implanted

COUNT X
Loss of Consortium

126. Plaintiffs incorporate by reference the allegations in all prior paragraphs.

127. Plaintiff Alicia Morz De Milanesi was and is the lawful spouse of Plaintiff Antonio Milanesi and in such capacity, was and is entitled to the comfort, enjoyment, society, and services of her spouse.

128. As a direct and proximate result of the foregoing allegations, Plaintiff Alicia Morz De Milanesi was deprived of the comfort, enjoyment, society, and services of her spouse, has suffered and will continue to suffer economic loss, and otherwise has been emotionally and economically injured. Plaintiff Alicia Morz De Milanesi's injuries and damages are permanent and will continue into the future.

PUNITIVE DAMAGES

129. Plaintiffs incorporate by reference the allegations in all prior paragraphs.

130. Defendants sold their products to healthcare providers throughout the United States without doing adequate testing to ensure that the products were reasonably safe for implantation.

131. Defendants sold their products to healthcare providers throughout the United States in spite of their knowledge that the products pose risks of degradation, infection, contracture, shrinkage, breakage, separation, tearing, splitting, and other problems, thereby causing severe and debilitating injuries suffered by the Plaintiff Antonio Milanesi.

132. Defendants ignored reports from patients and healthcare providers throughout the United States and elsewhere of the products' failures to perform as intended, which lead to the severe debilitating injuries suffered by the Plaintiff Antonio Milanesi. Rather than doing adequate testing to determine the cause of these injuries, or to rule out the products' designs or the processes by which the products are manufactured as the cause of these injuries, Defendants chose instead to continue to market and see the products as safe and effective.

133. Defendants knew the products were unreasonably dangerous in light of their risks of failure resulting in pain and suffering, loss of life's enjoyment, remedial surgeries and treatments in an effort to cure the conditions proximately related to the use of the products, as well as other severe injuries which are permanent and lasting in nature.

134. Defendants withheld material information from the medical community and the public in general, including the Plaintiff Antonio Milanesi, regarding the safety and efficacy of the product.

135. Defendants knew and recklessly disregarded the fact that the products caused debilitating and potentially life-altering complications with greater frequency than feasible alternative methods and/or products.

136. Defendants misstated and misrepresented data, and continue to misrepresent data, so as to minimize the perceived risk of injuries caused by the products.

137. Notwithstanding the foregoing, Defendants continue to aggressively market the products to consumers, without disclosing the true risks associated with the products.

138. Defendants knew of the products' defective and unreasonably dangerous nature, but continued to manufacture, market, distribute, and sell the products so as to maximize sales and profits at the expense of the health and safety of the public, including the Plaintiff Antonio Milanesi.

139. Defendants continue to conceal and/or fail to disclose to the public, including the Plaintiff Antonio Milanesi, the serious complications associated with the use of the products, to ensure continued and increased sales.

140. Defendants conduct as described herein shows willful misconduct, malice, fraud, wantonness, oppression or that entire want of care which raises the presumption of conscious indifference to consequences, thereby justifying an award of punitive damages.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs demand judgment against Defendants for an amount in excess of $75,000.00, individually, jointly and severally, and pray for the following relief in accordance with applicable law and equity:

i. Compensatory damages for past, present, and future damages, including but not limited to, pain and suffering for severe and permanent personal injuries sustained by Plaintiffs, permanent impairment, mental pain and suffering, loss of enjoyment of life, loss of consortium, health and medical care costs, economic damages, together with interest and costs as provided by law;
ii. restitution and disgorgement of profits;
iii. punitive damages;
iv. reasonable attorneys' fees as provided by law;
v. costs of these proceedings, including past and future costs of suit;

vi. all ascertainable economic damages;
vii. prejudgment interest on all damages as allowed by law; and
viii. such other and further legal and equitable relief as this Court deems just and proper.

DEMAND FOR TRIAL BY JURY

Plaintiffs hereby demand a trial by jury on all issues so triable.

Dated: October 26, 2018

Respectfully submitted,

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